

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-608V

Filed: May 25, 2007

STEPHEN AND MARGARET RICCA)	
parents of minor child,)	
MICHAEL RICHARD RICCA)	UNPUBLISHED
)	
)	Motion for Judgment on the
)	Record; Pediarix vaccine;
Petitioners,)	Seizures; Developmental delay;
)	No offered medical theory or
v.)	expert opinion causally
)	connecting the vaccination
SECRETARY OF THE DEPARTMENT)	and the alleged injury
OF HEALTH AND HUMAN SERVICES,)	
)	
Respondent.)	
)	

Thomas P. Gallagher, Somers Point, NJ, for petitioner.

Melonie J. McCall, with whom were Peter D. Keisler, Assistant Attorney General, Timothy P. Garren, Director, Mark W. Rogers, Deputy Director, and Gabrielle M. Fielding, Assistant Director, United States Department of Justice, Torts Branch, Civil Division, Washington, DC, for respondent.

DECISION¹

On August 29, 2006, petitioners, Stephen and Margaret Ricca, as parents of the minor child Michael Ricca, filed a petition pursuant to the National Vaccine Injury

¹ Vaccine Rule 18(b) states that all of the decisions of the special masters will be made available to the public unless an issued decision contains trade secrets or commercial or financial information that is privileged or confidential, or the decision contains medical or similar information the disclosure of which clearly would constitute an unwarranted invasion of privacy. When a special master files a decision or substantive order with the Clerk of the Court, each party has 14 days within which to identify and move for the redaction of privileged or confidential information before the document's public disclosure.

Compensation Program² (the Act or the Program), 42 U.S.C. § 300aa-10 et seq. Petitioners allege that Michael received a “diphtheria-pertussis-tetanus [acellular] vaccine (hereinafter “[DTaP]”), [h]aemophilus influenza type B vaccine (hereinafter “[Hib]”), and pneumococcal conjugate vaccine (hereinafter “[PCV7]”) . . . on November 23, 2004 and . . . thereafter suffered seizures which progressed to infantile spasms, delayed development, and axial hypotonia.” Petition (Pet.) at 1 (emphasis omitted). The petition states that Michael’s “brain injury and . . . seizure disorder . . . [were] caused-in-fact by the DPT vaccine.”³ *Id.* ¶ 8. The petition further states that Michael’s “developmental delay is a sequela of that brain injury and convulsive disorder.” *Id.* (citation omitted).

Together with the petition, Mr. and Mrs. Ricca filed: (1) a copy of Michael’s birth certificate, *see* Petitioners’ Exhibit (Ps’ Ex.) 1; (2) Mrs. Ricca’s pre-natal medical records, *see* Ps’ Ex. 2; (3) Mrs. Ricca’s labor and delivery records, *see* Ps’ Ex. 3; (4) Michael’s pediatric progress notes between July 2004 and October 2005, *see* Ps’ Ex. 4; (5) Michael’s immunization record, *see* Ps’ Ex. 5; (6) Mr. Ricca’s affidavit, *see* Ps’ Ex. 6; (7) Mrs. Ricca’s affidavit, *see* Ps’ Ex. 7; (8) Michael’s medical records from Jersey Shore University Hospital, *see* Ps’ Ex. 8; and (9) Michael’s medical records from The Children’s Hospital of Philadelphia, *see* Ps’ Exs. 9-12. After filing the petition with the described exhibits, petitioners retained Mr. Thomas Gallagher as counsel. *See* Petitioners’ Motion to Substitute Counsel filed 10/30/06. On petitioners’ behalf, counsel filed additional medical records from The Children’s Hospital of Philadelphia, *see* Ps’ Exs. 13, 15, and Michael’s medical records from the office of Dr. Peter Halas, a pediatrician, *see* Ps’ Ex. 14.

Respondent filed a Rule 4(c) Report (R’s Rept.) on November 27, 2006. In the Rule 4(c) Report, respondent asserted that petitioners were not entitled to Program compensation because petitioners had not established by a preponderance of the evidence that Michael’s vaccinations caused his injuries. R’s Rept. at 7, 10. Specifically, respondent stated, petitioners have not yet presented “a reliable medical or scientific theory causally connecting Michael’s vaccination to any alleged injury,” have not yet identified a logical cause and effect sequence between Michael’s vaccination and infantile spasms, and have not yet offered an opinion of causation from either an expert or

² Hereinafter, for ease of reference, all “section” references to the Vaccine Injury Compensation Act will be to the pertinent subdivision of 42 U.S.C. § 300aa (2006 ed.).

³ Michael’s immunization record indicates that he received a Pediarix vaccination on November 23, 2004. Ps’ Ex. 4 at 3; Ps’ Ex. 5 at 1. Pediarix is combination vaccination comprised of diphtheria and tetanus toxoids, acellular pertussis adsorbed, recombinant hepatitis B, and inactivated poliovirus. *See* http://www.pediarix.com/what_is_pediarix.htm.

a treating physician. Id. at 9-10.

Petitioners filed no additional medical records. Nor did petitioners file an expert opinion. Rather, on February 5, 2007, petitioners filed a one-sentence Motion for Judgment on the Record (Ps' Mot.). With the motion was an affidavit from counsel stating that counsel "had contacted [Dr.] Marcel Kinsbourne, [a neurologist,] for purposes of obtaining an expert report in this matter and [that Dr. Kinsbourne] was unable to opine that the vaccinations caused [the] infant's problems." Ps' Mot., Counsel's Affidavit ¶ 3. Counsel explained to petitioners that they could not prove causation "without an expert report." Id. ¶ 4.

Petitioner's motion for judgment on the record is now ripe for decision.

I. DISCUSSION

A. The Factual Record

Petitioners' son, Michael, was born by caesarean section on July 21, 2004. Ps' Ex. 1 at 1. The filed medical records indicate that Michael was "tachypneac"⁴ at birth. Ps' Ex. 3 at 2. He was treated with antibiotics for suspected "sepsis" infection. Id. at 7, 9, 13. His cultures were negative, however, and his respiratory status improved. Id. at 13. Mrs. Ricca and Michael were discharged from the hospital, with no complications, four days after Michael's birth. See id. at 2, 7.

During a well-child examination on September 27, 2004, Michael received his first dose of DTaP,⁵ Hib,⁶ pneumococcal heptavalent conjugate ("PCV7")⁷, inactivated polio

⁴ Tachypnea is an "excessive rapidity of breathing." Dorland's Illustrated Medical Dictionary, supra note 1, at 1851.

⁵ The DTaP vaccine is "a combination of diphtheria toxoid, tetanus toxoid, and pertussis vaccine; administered intramuscularly for simultaneous immunization against diphtheria, tetanus, and pertussis." Dorland's Illustrated Medical Dictionary 1998 (30th ed. 2003).

⁶ The haemophilus influenzae type b vaccine protects against infection by the haemophilus influenzae type b bacterium. Dorland's Illustrated Medical Dictionary, supra note 2, at 1999.

⁷ The PCV7 vaccine is administered intramuscularly and contains "purified polysaccharides of the capsular antigens of [seven] Streptococcus pneumoniae serotypes . . . individually coupled with to a nontoxic variant of diphtheria toxin . . ." Dorland's Illustrated

(IPV) and Hepatitis B (Hep B) vaccines. Ps' Ex. 4 at 3; Ps' Ex. 5 at 1. During a subsequent well-child examination on November 23, 2004, Michael received his second dose of DTaP, Hep B, IPV, Hib, and PCV7 vaccines. Ps' Ex. 5 at 1.

Michael's medical records show that on January 6, 2005, nearly six weeks after he received the second dose of DTaP and other vaccines, Michael was admitted to the Jersey Shore University Medical Center with a five-day history of episodic seizures lasting 45 to 60 seconds. See Ps' Ex. 8 at 1-2. Based on an abnormal electroencephalogram ("EEG"),⁸ Michael was diagnosed with "seizure disorder, partial seizure, [and] adverse seizure." Id. at 1, 11. Although he was prescribed three medications to control his seizures, specifically, Dilantin, Phenobarbital and Trileptal, Michael's seizures continued. Id. 8 at 1, 7.

Michael received further evaluation of his seizures at the Children's Hospital of Philadelphia (CHOP) during a five-day admission and during subsequent outpatient visits. See Ps' Exs. 9-13, 15. After various physical examinations and administered tests during his CHOP's admission between January 12, 2005 and January 17, 2005, Michael was diagnosed with infantile spasms of unknown etiology. Ps' Ex. at 9 at 2, 6. During follow-up examinations at CHOP and subsequent examinations by Michael's pediatrician between January 2005 and April 2005, delays in Michael's development were noted. See Ps' Ex. 4 at 12; Ps' Ex.10 at 1-3.

After consultation with the physicians at CHOP, Michael's pediatrician administered his third dose of DTaP, Hep B, IPV, and PCV7 vaccines on April 21, 2005. Ps' Ex. 4 at 12; Ps' Ex. 5 at 1. Physical therapy sessions and developmental intervention sessions were added to Michael's schedule in 2005. See Ps' Ex. 13 at 19, 21-23. During Michael's last neurological examination of record, which occurred on August 16, 2006 when Michael was twenty-five months old, the examining neurologist, Dr. Amy Waldman noted that Michael's language skills were approximately 10 months delayed, and that he was behind in some of his vaccinations. Ps' Ex. 13 at 29-30.

Medical Dictionary, supra note 1, at 1999.

⁸ An EEG is "a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain. . . . Fluctuations in potential are seen in the form of waves, which correlate well with different neurologic conditions and so are used as diagnostic criteria." Dorland's Illustrated Medical Dictionary, supra note 2, at 596.

B. Legal Standard and Analysis

The Vaccine Act permits petitioners to prove entitlement to compensation by showing that either: (1) the vaccinee suffered an injury listed on the Vaccine Injury Table within the prescribed time period, commonly referred to as a “Table” case, see § 300aa-14(a); or (2) the vaccinee suffered an injury that is not listed on the Vaccine Injury Table but is caused in fact by the received vaccination, commonly referred to as an “off-Table” case, see § 300aa-11(c)(1)(C)(ii)(I). By either method, petitioners bear the burden of proving their claim by a preponderance of the evidence. § 300aa-13(a)(1).

In a “Table” case, petitioners benefit from a presumption of causation. See § 300aa-14(a); 42 C.F.R. § 100.3(a). Here, Michael’s seizures did not begin until nearly six weeks after the receipt of his vaccinations. The record in this case does not support a finding that a Table injury occurred.

Accordingly, to establish entitlement to Program compensation, petitioners must prove, by a preponderance of the evidence, their “off-Table” claim that the DTaP vaccination that Michael received on November 23, 2004, caused his seizures and developmental delay. Petitioners satisfy their burden of proof “by providing: (1) a medical theory causally connecting [Michael’s] vaccination and [his] injury; (2) a logical sequence of cause and effect showing that [Michael’s] vaccination was the reason for [his] injury; and (3) a showing of a proximate temporal relationship between [Michael’s] vaccination and injury.” Althen v. Sec’y of Dept. of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

In this case, petitioners have failed to supply any evidence of a causal connection between Michael’s vaccination and his seizure disorder. Michael’s medical records do not establish any relationship between his vaccination and his condition. Nor have petitioners provided an expert opinion offering a medical theory causally connecting Michael’s vaccination to his episodic seizures. Instead, petitioners have conceded that they are unable to obtain an expert opinion to support their claim of causation. Ps’ Mot., Counsel’s Affidavit ¶ 4.

The Vaccine Act prohibits a special master from making a finding of entitlement to compensation based on the claims of petitioners alone, without substantiation by medical records or by a medical opinion. See § 300aa-13(a)(1). In this case, petitioners claim is not substantiated by either the filed medical records or an offered medical opinion. Under the Vaccine Act, petitioners’ claim must fail.

II. CONCLUSION

The medical records in this case do not establish a causal connection between Michael's second DTaP vaccination and his seizure disorder. Petitioners have offered no medical opinion causally connecting Michael's vaccination and his condition. Because petitioners have failed to establish entitlement to compensation under the Vaccine Act, petitioners' claim is **DISMISSED**. The Clerk of the Court shall **ENTER JUDGMENT** accordingly.⁹

IT IS SO ORDERED.

Patricia E. Campbell-Smith
Special Master

⁹ Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of notice renouncing the right to seek review.